UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

APR 17 1991

In re Pfizer Hospital Products Group, Inc.	: DECISION ON APPLICATION
U. S. Patent No. 4,621,638	: FOR EXTENSION OF PATENT
	: TERM UNDER 35 U.S.C. § 156

An application for extension of the term of U.S. Patent No. 4,621,638 granted November 11, 1986, which claims a product drawn to a medical device was filed under 35 U.S.C. § 156 in the Patent and Trademark Office (PTO) on February 22, 1991. The medical device claimed by the '638 patent is the Dekantel Microflex Ophthalmic Suture. The application was filed by the patent owner Pfizer Hospital Products Group, Inc. (Pfizer).

The application raises a question of eligibility for patent term extension of a patent claiming a product drawn to a medical device wherein permission to market the device was not approved by the Food and Drug Administration (FDA) under section 515 of the Federal, Food, Drug and Cosmetic Act (FFDCA), but instead was authorized under section 510 (k) of the FFDCA. For the reasons set forth below, the application for extension of the term of the '638 patent is denied.

DISCUSSION

Section 156 (a) (4) of Title 35 permits the term of a patent claiming a medical device which was subject to a "regulatory review period" before its commercial marketing or use to be extended for a period of time equal to a calculated portion of the regulatory review period which occurred after the patent was issued. Under the terms of 35 U.S.C. § 156 (g) (3) (B), the "regulatory review period" for a medical device is limited to a regulatory review which was conducted under section 515 of the FFDCA to the exclusion of a regulatory review conducted under section 510 (k) of the FFDCA. See In re Nitinol Medical Technologies Inc., 17 USPQ2d 1492 (Comm'r Pat. 1990). Accordingly, in order to be eligible for an extension of the term of the patent, the medical device must have been subject to a regulatory review under section 515.

Pfizer asserts that the product (medical device) was subject to regulatory review under section 515 of the FFDCA, noting that the product was originally classified as a Class III device subject to section 515 review and subsequently reclassified by the FDA as a Class II device (application, ¶ 2). The product, a non-absorbable polypropylene suture, was assigned to Class III because it is a "transitional device" which was regulated as a new drug before 1976. Accordingly, as the suture was subject to FDA premarketing approval as a Class III device, an Investigational Device Exemption (IDE) application filed by applicant was approved on March 11, 1988. During the time the human clinical studies were being conducted under the IDE, the FDA, on July 5, 1990, reclassified this type of suture material a Class II device (application, ¶ 2). At the conclusion of the clinical studies a section 510 (k) application was filed with the FDA instead of a section 515 application since the device had been reclassified into Class II (application, ¶ 9). Pfizer states that while final approval was based upon a section 510 (k) submission, prior extensive testing was governed by the provisions of section 515 of the FFDCA (application, ¶ 3).

Pfizer's position that the initial regulatory review of the medical device under section 515 as a Class III device prior to its reclassification by the FDA to a Class II device and subsequent approval under section 510 (k) satisfies the "regulatory review period" requirement of the statute is not tenable. This issue addresses the specific eligibility requirements set by Congress for patent term restoration under section 156 (a) (4).

Section 156 (a) (4) provides:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if - ...
>
> > (4) the product has been subject to a regulatory review period before its commercial marketing or use; ... (emphasis added).

The term "regulatory review period" is defined in section 156 (g) (3) which provides:

> (A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) ...
>
> (B) The regulatory review period for a medical device is the sum of - -
>
> > (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515 (f) (5) and ending on the date the protocol was declared completed under section 515 (f) (6) (emphasis added).

The reference to section 515 is a reference to section 515 of the FFDCA. See 35 U.S.C. § 156 (f) (4).

The starting point for statutory interpretation is the plain language of the statute. Unless it is ambiguous, the language Congress chose is conclusive of its meaning absent a clearly stated contrary intention. Burlington Northern R.R. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461 (1987). As noted above, the regulatory review period of a medical device under section 156(g)(3)(B) is the sum of the requirements of subsections (i) and (ii). The plain language of the statute clearly states that both subsections (i) and (ii) must be satisfied. Subsection (i) requires a clinical investigation of the device on humans which ends on the date an application under section 515 is filed. While a clinical investigation was conducted, it did not end with the filing of an application under section 515, but with the filing of a section 510 (k) application. Accordingly, the regulatory review of the medical device which is the subject of the patent term extension application does not satisfy the requirements of subsection (i). Subsection (ii) requires either (1) that an application be filed and completed under section 515 or (2) that a product development protocol be submitted and completed under section 515 (f). Neither of these requirements have been satisfied. Accordingly, the regulatory review of the medical device which is the subject of the patent term extension application does not satisfy the requirements of subsection (ii). Although applicant has undertaken regulatory review for the medical device under section 510(k), the statute does not authorize patent term extension for this type of regulatory review.

Thus, Congress clearly intended that the medical device be approved for marketing under a regulatory review having a testing phase and an approval phase under section 515 of the FFDCA to be eligible for patent term extension.

DECISION

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. 4,621,638 is not eligible for extension of the patent term under 35 U.S.C. § 156. The

Dekantel Microflex Ophthalmic Suture has not been subject to a "regulatory review period" within the meaning of 35 U.S.C. § 156 (a) (4) as defined in 35 U.S.C. § 156 (g) (3). Accordingly, the application for extension of the term of U.S. Patent No. 4,621,638 is denied.

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Re: Dekantal Microflex
Ophthalmic Suture

FDA Docket No. 91E-0091

cc: John L. LaPierre
Pfizer Inc.
Patent Department
235 East 42nd Street
New York, NY 10017-5755

(For Patent Owner)